#### **REMARKS**

### Claim Amendment and Support Therefor

Claims 1-27, 30 - 32, and 34 - 39 have been cancelled without prejudice to their presentation in a continuing application. Applicants do not abandon the inventions of the of non-elected claims.

Claim 33, objected to by the Examiner, but otherwise allowable, has been recast in independent form.

New Claim 40 is the original Claim 11 recast as dependent on Claim 33.

New Claim 41 has been added. Claim 40 is directed to a pharmaceutical composition that comprises amonafide glycolate. Support for this claim is found throughout the specification and, for example, in Claim 10 as originally filed.

New Claim 42 is the original Claim 11 recast as dependent on Claim 41.

New Claims 43-52 have been added.

Claims 43, 45, 47, 49 and 51 are directed to the subject matter of Claim 36, objected to by the Examiner but otherwise allowable. Recitation by new Claims 43, 45, 47, 49 and 51 of amonafide glycolate is supported throughout the specification and, for example, in Claim 10 as originally filed.

Claims 44, 46, 48, 50 and 52 are all the original Claim 11 recast as dependent on Claims 43, 54, 47, 49 and 51.

This amendment introduces no new matter.

## Rejection of Claims 1-29, 30-32, 34-35 and 37-39 under 35 U.S.C. §103(a)

Claims 1-29, 30-32, 34-35 and 37-39 stand rejected as being obvious over Brana I (U.S. Patent 4,204,063) in view of Brana II (U.S. Patent 5,420,137), Zee-Cheng (U.S. Patent 4,614,820), and Berge *et al.*, "Pharmaceutical Salts", *J. of Pharm. Sci.* 66(1): 1-19 (1977).

The Examiner maintained the previously advanced rejection based on a contention that carboxylic acid salts of basic pharmaceutical ingredients are known and replacing mineral (inorganic) counterions of amonafide with organic counterions would have been obvious. The Examiner stated that data presented in Tables 3 and 4 of the instant specification fails to provide

sufficient evidence of unexpected properties of the claimed salts of amonafide in comparison with the previously disclosed inorganic salts.

#### Examiner's Interview

An Examiner's interview took place in the Offices of the USPTO on January 25, 2005. Applicants were represented by Dr. Alfred Ajami, Steven Davis, Esq. and Alexander Akhiezer, Ph.D. Examiner Evelyn M. Huang represented the USPTO.

In the course of the interview, data in support of an assertion of unexpected properties of the organic carboxylic salts of amonafide was discussed. The Examiner suggested that data in addition to the data included in the specification be presented. The Examiner further stated that statistically significant additional data would reflect favorably on patentability of the claims currently pending.

Applicants agreed to present new supporting data.

# Applicants' Response

Applicants believe that the present Amendment places Claim 33 as amended as well as new Claims 40-52 in condition for allowance. Recitation by the new claims of amonafide glycolate is supported by the specification and the claims as originally filed. Applicants further note that claims directed to amonafide glycolate were allowed in the parent application, now issued U.S. Patent No. 6,693,198.

## **CONCLUSION**

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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